

## REMARKS

### Benefit of Prior Applications:

In response to pages 2 and 3 of the Action, Applicants with this Amendment have submitted a Petition under 37 CFR 1.78(a)(3) to accept a delayed claim benefit under 35 USC 120 of a prior filed copending nonprovisional application. Applicants request that the Petition be considered and granted.

On page 4 of the Action, claims 10, 11, and 12 have not been granted priority to the parent applications which are included in the Petition. Applicants acknowledge the Examiner's decision and have cancelled those claims.

Applicants believe that the objections on pages 2-4 have been addressed by this Response and respectfully request that they be removed.

### Rejections under 35 USC 112:

Claim 1 has been rejected for lack of antecedent basis.

Claim 1 has been amended to delete the terminology "nucleic acid" and insert the term "protein" in its place. The term "protein" has antecedent basis in the claim preamble. Therefore, the rejection is believed to be obviated.

Applicants acknowledge the rejection withdrawals on pages 5 and 6 of the Action.

### Double Patenting:

On pages 7 and 8, the rejection for Double Patenting has been maintained.

With this Amendment, Applicants have filed a Terminal Disclaimer as suggested in the Action to obviate this rejection. Applicants request that the rejection be removed.

Rejection under 35 USC 102:

Claims 1, 3-6, 8, 13, 15 and 16 have been rejected under §102 as being anticipated by Makino *et al.*

Applicants have amended the Specification to include parent applications that pre-date the Makino reference. Additionally, Applicants have amended claim 1 to include the terminology “inserting the polynucleotide, which is not complexed with another molecule.” The added terminology is directed to the Makino reference in which Makino uses a complex consisting of oligonucleotide and poly(L)lysine. The poly(L)lysine is a known delivery enhancing molecule.

Support for this amendment can be found in each example where naked polynucleotides are used.

Claims 1, 3-5, 9, 10, 13, 14 and 15 have been rejected under §102 as being anticipated by Wianny *et al.* Wianny disclose injecting into the uteri of mice. The Action states that a uterus could be considered a “vessel” as claimed.

Applicants have amended claim 1 to delete the term “vessel” and substitute the following terminology: wherein the vessel consists of arteries, arterioles, capillaries, venules, sinusoids, veins, lymphatics, and bile ducts. Applicants believe that this terminology removes Wianny *et al.* as a prior art consideration to their application.

Rejection under 35 USC 102:

Claims 1 and 7 have been rejected under §102 for being anticipated by Kay *et al.* The Action states that Kay delivered adenovirus through the bile duct.

Applicants have amended claim 1 to be limited to a polynucleotide, which is not complexed with another molecule. A virus inherently requires the encapsulated polynucleotide to be complexed with many other molecules, where the viral complex is required for polynucleotide delivery. Applicants believe that the Kay rejection has been overcome by their amendment.

Rejection under 35 USC 103:

Claims 1, 3-5 and 9-15 have been rejected under §103 for being obvious when taking into consideration the Wianny *et al.* reference along with Caplen *et al.*

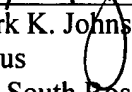
Applicants believe that they have addressed the §103 rejection with their §102 arguments put forth earlier in this Response. The Wianny reference is believed to be overcome by the current amendments.

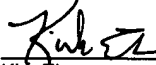
Declaration under 37 CFR 1.131:

With this Response, Applicants have included a §1.131 Declaration to establish invention for delivery of short polynucleotides prior to the effective dates of the cited references. This Declaration is meant to supplement the amendments that have been made in this Response and further solidify Applicants' position in this field.

The Examiner's objections and rejections are now believed to be overcome by this response to the Office Action. In view of Applicants' amendment and arguments, it is submitted that claims 1, 3-9 and 13-16 should be allowable.

Respectfully submitted,

  
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Mark K. Johnson Reg. No. 35,909  
Mirus  
505 South Rosa Road  
Madison, WI 53719  
608-238-4400

<p>I hereby certify that this correspondence is being sent by facsimile transmission to: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450 on this date: <u>7/30/04</u></p> <p> _____ Kirk Ekena</p>
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